DEC 13 2012

510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the Medlinx Surgical Mesh is provided below.

Device Common Name:	Polymeric Surgical Mesh
Device Proprietary Name:	Medlinx Surgical Mesh
Submitter:	Medlinx Acacia Pte Ltd 10 Anson Road #31-10 International Plaza Singapore 079903
Date Prepared:	November 6, 2012
Classification Regulation:	21 CFR 878. 3300
Class:	II
Panel:	General & Plastic Surgery Devices
Product Code:	FTL
Predicate Devices:	Ethicon, Inc's ULTRAPRO Mesh (K033337) C.R. Bard's Marlex Mesh (K922916)

Indication for Use:
The Medlinx Surgical Mesh is intended to be implanted to reinforce soft tissue where weakness exists for the repair of hernias and other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Device Description:
The Medlinx Surgical Mesh is a sterile, implantable, single-layer polymeric mesh that is comprised of non-absorbable polyvinylidene fluoride (PVDF) and absorbable poly(1,4-butylene adipate) (PBA). The PBA plasticizer increases the flexibility of the mesh, and it is partially absorbed once implanted.

Comparison to the Predicate
The Medlinx Surgical Mesh has similar indications for use and technological characteristics as Ethicon Inc.'s UltraPro Mesh and C.R. Bard's Marlex Mesh. All

three meshes are manufactured with a non-absorbable polymer material. The Medlinx Surgical Mesh and the UltraPro Mesh both have a partially absorbable polymer material. All three are available in a similar range of sizes.

Mechanical testing, biocompatibility testing and animal testing were conducted per the recommendations in: *Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance – Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," dated March 2, 1999."* The following tests were conducted:

Biocompatibility Testing
In Vitro Cytotoxicity
Skin Sensitization (Maximization Method)
Intracutaneous Reactivity
Acute Systemic Toxicity
In Vitro Bacterial Reverse Mutation (AMES)
In Vitro Chromosome Aberration
In Vitro Mammalian Cell Gene Mutation
Intramuscular Implantation
In Vitro Hemolysis
Pyrogenicity
Sub-Chronic Systemic Toxicity

Bench Testing
Mesh Density
Tensile Strength
Device Stiffness
Suture Pullout Strength
Burst Strength
Tear Resistance
Residual levels of heavy metals
Polymer purity
Biodegradation
PBA Extraction
Expiration Dating

The biocompatibility testing showed the comparable safety profile of the Medlinx Surgical Mesh and the predicates. Bench testing demonstrated that the device is substantially equivalent for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics and performance test results, the Medlinx Surgical Mesh is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

Medlinx Acacia Pte Ltd
% Biologics Consulting Group
Mr. Stephen P. Rhodes
Senior Consultant, Medical Devices
3502 Dundee Drive
Chevy Chase, Maryland 20815

Re: K120844
Trade/Device Name: Medlinx Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: December 13, 2012
Received: December 13, 2012

Dear Mr. Rhodes:

This letter corrects our substantially equivalent letter of December 13, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

3.0 Indications for Use Statement

510(k) Number (if known): K120844

Device Name: Medlinx Surgical Mesh

Indications for Use:

The Medlinx Surgical Mesh is intended to be implanted to reinforce soft tissue where weakness exists for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K120844